IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	)	C. A. No. 06-222 (JJF) **REDACTED - PUBLIC VERSION**

WYETH'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO STRIKE PARAGRAPHS 72-73, 81-84, 129-130 AND 133-136 OF THE REBUTTAL EXPERT REPORT OF ARTHUR H. KIBBE, Ph.D.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 N. Market Street
Wilmington, DE 19899-1347
(302) 658-9200
klouden@mnat.com
Attorneys for Plaintiff Wyeth

OF COUNSEL:

Basil J. Lewris
Linda A. Wadler
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, DC 20001
(202) 408-4000

Original Filing Date: December 28, 2007

Redacted Filing Date: January 8, 2008

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

OTHER AUTHORITIES

INTRODUCTION

Impax's Opposition correctly articulates a basic tenet of patent law: To determine whether the claims at issue are invalid, the Court must first construe the claims. Under the Court's Scheduling Order, Impax was required to set forth the invalidity positions and arguments of its experts, including any and all claim constructions necessary to establish invalidity, no later (and arguably much earlier, during the Markman proceedings) than with its initial round of expert reports, which were due on September 28, 2007. (D.I. 27 at ¶ 3(e)). The Scheduling Order provided for rebuttal expert reports on October 31, 2007, thereby allowing Wyeth's experts an opportunity to respond to any invalidity opinions set forth in Impax's initial expert reports. (*Id.*)

Rather than comply with the Scheduling Order, Impax inexplicably waited until its rebuttal expert reports, which should have been limited to the issue of infringement, to proffer new claim construction and invalidity opinions for the first time. Because Impax proffered those new opinions well past the Court's deadline, and at a point where Wyeth had no authorized opportunity to respond, those opinions unfairly prejudice Wyeth and should be stricken.

ARGUMENT

Impax has framed the issue as whether "the challenged paragraphs in Dr. Kibbe's rebuttal report respond to the opinions put forward by Wyeth's experts, or do they instead raise new, non-responsive arguments?" (D.I. 307 at 6). The answer is clear: because they raise new invalidity opinions, and do **not** address infringement, they are without a doubt new, non-responsive arguments.

In their reports, Wyeth's experts established that Impax's proposed products meet each and every claim term of the asserted claims. As part of their infringement analysis,

Wyeth's experts provided their interpretation of the asserted claim terms that they then applied to the proposed products.

Impax's experts, on the other hand, inexplicably failed to include in their initial expert reports the claim interpretations on which they relied for their invalidity opinions. Instead, they waited until the last round of reports, depriving Wyeth of any opportunity to respond.

Contrary to Impax's assertion, Wyeth did not argue that Impax should not have "addressed claim construction in either [its opening or rebuttal expert] report." (D.I. 307 at 6). Rather, Wyeth contends that Impax's experts should have addressed any claim construction issues relevant to their invalidity opinions, for which Impax bears the burden of proof, no later than in their opening expert reports, as required by the Court's Scheduling Order, so that Wyeth could properly respond to those opinions in its rebuttal expert reports. (*See* D.I. 27 at ¶ 3(e)). Indeed, Fed. R. Civ. P. 26(a)(2)(B) requires that an "[expert] report shall contain a complete statement of all opinions to be expressed and the basis and reasons therefore." These "disclosures shall be made at the times and in the sequence directed by the court." Fed. R. Civ. P. 26(a)(2)(C). Accordingly, Impax's argument that, should the Court decide to strike the contested paragraphs in Dr. Kibbe's rebuttal expert report, it should also "preclude Wyeth's experts from submitting claim interpretation opinions" in their opening expert reports, lacks merit. (D.I. 307 at 12).

Impax further argues that Dr. Kibbe's new opinions are proper because Impax should be permitted to rebut the opinions of Wyeth's experts "both in the context of discussing infringement *and* invalidity." (D.I. 307 at 8). That is not what occurred here, however. Dr. Kibbe did not argue in his rebuttal report that, under the constructions proffered by Wyeth's

experts, the claims would be invalid. To the contrary, Dr. Kibbe proffers his own constructions and argues invalidity based on them. REDACTED

REDACTED

REDACTED This argument has nothing to do with rebutting the infringement opinions of Wyeth's experts.

Moreover, Impax's incorrect argument that Dr. Kibbe was merely responding to the claim construction opinions of Wyeth's experts misses the point. Impax's claim construction and invalidity positions were, or should have been, available to Impax long before Wyeth proffered its initial expert reports. For example, with respect to the "about 150 ng/ml" limitation,

REDACTED

REDACTED Furthermore, Impax had access to Wyeth's patents-in-suit and their prosecution histories since at least the beginning of this action. It is, therefore, unclear, and Impax provides no explanation, why Dr. Kibbe could not have formed his opinion

REDACTED

assess whether, and explain why, REDACTED

REDACTED Again, in this context, Impax had the affirmative obligation to raise this issue no later than in its initial expert reports. Impax failed to do so.

Impax further concedes that paragraph 130 of Dr. Kibbe's rebuttal report, which opines on REDACTED "does not even rise to the level of rebuttal argument," but rather "re-visits an opinion first raised in his [Dr. Kibbe's] Supplemental Report." (D.I. 307 at 7). Accordingly, Impax's own characterization of paragraph 130, and by implication paragraphs 82-83 and 129 (to which paragraph 130 relates), shows that those paragraphs ***do not*** respond to Wyeth's reports. Rather, these paragraphs admittedly directly relate to invalidity opinions that should have been addressed in Impax's opening expert reports. By "re-visiting" that opinion in Dr. Kibbe's rebuttal report, Impax is attempting to supplement Dr. Kibbe's opening report a ***second*** time by introducing new invalidity defenses in violation of the Scheduling Order.

As for the claim terms "spheroid" and "encapsulated," Impax ***admits*** that it had already expressly agreed to Wyeth's construction of these terms. (D.I. 307 at 2; *see also* D.I. 298, Exs. E-H). And although Impax correctly notes that Dr. McGinity offered definitions of "spheroid" and "encapsulated" in his initial report, Impax neglects to mention that they were the *verbatim* definitions to which the parties agreed. (Compare D.I. 308, Ex. A at ¶¶ 54-55 to D.I. 298, Exs. E-H). It is Impax that seeks to change these constructions in its rebuttal reports. Had Impax wanted to further argue REDACTED

REDACTED as Dr. Kibbe does now in his rebuttal report, Impax should have done so long ago.

As for the claim term "therapeutic metabolism," Wyeth believes that Dr. Kibbe's proposed opinion is now moot in light of Impax's indication in its proposed statement of issues of law and intended proofs that Impax "would have litigated" the indefiniteness of this claim term had the Court not adopted Wyeth's construction. (Ex. A at 17; Ex. B at 17). For avoidance of doubt, however, Wyeth notes that Impax argued in its May 8, 2007 claim construction brief that that claim term "therapeutic metabolism" is indefinite. Yet Dr. Kibbe failed to articulate this invalidity position in either his opening or unauthorized supplemental reports.

Having failed to proffer any rational explanation for those omissions, Impax is now trying for a third bite at the apple while at the same time depriving Wyeth of the ability to respond as contemplated by the Court's Scheduling Order.

Finally, in its opening brief, Wyeth analyzed the *Pennypack* factors that this Court considers when deciding whether to exclude testimony and cited to a number of cases where the court excluded untimely submissions.[1] (D.I. 297 at 6-8). Although Impax has attempted to characterize those cases as inapposite (D.I. 307 at 9-10), they clearly support the proposition that courts in this District and others routinely preclude untimely submissions, such as the challenged paragraphs in Dr. Kibbe's rebuttal report, when there is no reasonable justification for their untimeliness.

---

[1] *See e.g., Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894 (3d Cir. 1997); *AstraZeneca AB v. Mutual Pharm. Co.*, 278 F. Supp. 2d 491 (E.D. Pa. 2003); *Bridgestone Sports Co. Ltd. v. Acushnet Co.*, 2007 U.S. Dist. LEXIS 11370 (D. Del. Feb. 15, 2007); *Praxair, Inc. v. ATMI, Inc.*, 2005 WL 3159054 (D. Del. Nov. 28, 2005); *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 1996 U.S. Dist. LEXIS 22616, at *33-35 (D. Del. Dec. 27, 1996); *Matsushita Elec. Indus. Co., Ltd. v. Cinram Int'l, Inc.*, 299 F. Supp. 2d 348, 366 (D. Del. 2004); *The Liposome Co. v. Vestar, Inc.*, C.A. No. 92-332-RRM (D. Del. Nov. 24, 1993); *Stambler v. RSA Sec., Inc.*, 212 F.R.D. 470, 472 (D. Del. 2003); *AMEX, LLC v. Mopex, Inc.*, 215 F.R.D. 87 (S.D.N.Y. 2002); *Philips Elecs. N. Am. Corp. v. Contec Corp.*, 2004 U.S. Dist. LEXIS 5839, at *5 (D. Del. Apr. 5, 2004).

For example, in *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, the court precluded the defendant from presenting certain invalidity defenses because the defendant "had numerous opportunities to respond to [] discovery requests [that required disclosure of invalidity defenses] or to show why it should be relieved from having to respond," yet failed to do so. 1996 U.S. Dist. LEXIS 22616, *34-36 (D. Del. Dec. 27, 1996). The same logic applies here: Impax had many opportunities to disclose its new claim construction and invalidity opinions raised in Dr. Kibbe's challenged paragraphs (e.g., in response to Wyeth's interrogatories, in its claim construction briefing, in its opening expert reports), yet failed to do so.

Similarly, in *Bridgestone Sports Co. Ltd. v. Acushnet Co.*, the court precluded a defendant from relying on evidence "critical" to its invalidity defense because "the exclusion of this evidence will not cripple [the defendant's] invalidity case," "the parties [] are sophisticated business entities, leaders in their field, who are represented by counsel well-versed in complex patent litigation," and the reference relied upon in its untimely "invalidity contentions were available to [the defendant] before the close of fact discovery and well-before the [] deadline set by the Court" to make such disclosures. 2007 U.S. Dist. LEXIS 11370, *11-12 (D. Del. Feb. 15, 2007). Here, the contested paragraphs in Dr. Kibbe's report are not "critical" as Impax has raised other invalidity defenses, Impax is a sophisticated party represented by experienced litigation counsel, and Impax had many opportunities to disclose its untimely opinions well before the deadlines outlined in the Court's Scheduling Order.

Again, in *Praxair, Inc. v. ATMI, Inc.*, the court precluded the defendants from proving its invalidity case by relying on untimely submissions of prior art references that were not disclosed until after the court's discovery deadline. 2005 WL 3159054, *4 (D. Del. Nov. 28, 2005). And in *Philips Electronics North America Corp. v. Contec Corp.*, the court precluded a

party from relying on "untimely produced evidence" because the party had failed to persuade the court that it could not have produced the evidence earlier in accordance with the court's schedule. 2004 U.S. Dist. LEXIS 5839, *3 (D. Del. Apr. 5, 2004).

Although Impax argues that those cases are inapposite, which for the reasons explained above, they are not, Impax has not cited to **any** case where a court allowed a party to remain silent during both the Markman proceedings and its initial round of expert reports and then unveil new invalidity arguments for which it has the burden of proof at the eleventh hour, past the time for the other party to submit responsive expert reports, as Impax has done here. Such conduct should not be permitted.

CONCLUSION

For the foregoing reasons, Wyeth's Motion to Strike Paragraphs 72-73, 81-84, 129-130 and 133-136 of the Rebuttal Expert Report of Arthur H. Kibbe, Ph.D. should be granted.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs Louden (#2881)
Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 N. Market Street
Wilmington, DE 19899-1347
(302) 658-9200
klouden@mnat.com
Attorneys for Plaintiff Wyeth

OF COUNSEL:
Basil J. Lewris
Linda A. Wadler
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, DC 20001
(202) 408-4000

December 28, 2007

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on January 8, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
MORRIS JAMES LLP

I also certify that copies were caused to be served on January 8, 2008 upon the following in the manner indicated:

BY E-MAIL AND HAND

Mary B. Matterer
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19899

BY E-MAIL

Joseph C. Gratz
Daralyn J. Durie
KEKER & VAN NEST LLP
710 Sansome Street
San Francisco, CA 94111-1704

/s/ Karen Jacobs Louden

Karen Jacobs Louden (#2881)
klouden@mnat.com

EXHIBIT A

IMPAX'S STATEMENT OF ISSUES OF LAW TO BE LITIGATED

The following legal issues remain to be litigated.[1] To the extent that any of the issues of fact set forth in Impax's Statement of Issues of Fact That Remain to Be Litigated are properly considered issues of law, Impax incorporates those portions of that Statement herein by reference. To the extent any of the issues set forth in this Statement of Issues of Law That Remain to Be Litigated are properly considered issues of fact, Impax incorporates those portions of this Statement into its Statement of Issues of Fact That Remain to Be Litigated.

A. Impax would not infringe the patents-in-suit under the Impax construction of the claim term "extended release formulation."

1. Had this Court adopted Impax's proposed construction of the claim term "extended release formulation," the parties would have litigated whether Impax's accused extended-release venlafaxine product, if marketed and sold within the United States, would directly infringe any of the asserted claims of the patents-in-suit, either literally or under the doctrine of equivalents, or would indirectly infringe any of the asserted claims of the patents-in-suit, either by contributing to infringement of the claims in the United States or by knowingly inducing others to infringe the claims in the United States.

2. An infringement analysis consists of two steps. First, the Court determines the meaning and scope of the asserted patent claims. *See Aquatex Indus., Inc. v. Techniche Solutions,* 419 F.3d 1374, 1380 (Fed. Cir. 2005). Second, the properly construed claims are compared to the accused product or process. *See id.* Claims may be limited to process steps disclosed in the patent specification if such steps are an essential part of the claimed invention. *See Anderson Corp. v. Fiber Composites, LLC,* No. 05-1434, 06-1009, slip op. at 23 (Fed. Cir.

[1] In light of the Court's recent claim-construction ruling, and in order to create a record in case of appeal, Impax also intends to make an offer of proof regarding the evidence it would have presented regarding non-infringement and invalidity had the Court accepted Impax's proffered constructions of the disputed claim terms in the asserted claims of the patents-in-suit. In the interest of completeness, this list contains issues of law on which Impax intends to make such offers of proof.

invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Id.* at 1351.

8. **If the preambles of the asserted claims limit claim scope, any claims of the patents-in-suit using the phrase "therapeutic metabolism" would be invalid for indefiniteness under Impax's construction of the claim term "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma."**

52. Had this Court adopted Impax's proposed construction of the claim term "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma," and if the Court finds that the preambles of the asserted claims limit claim scope, the parties would have litigated whether the asserted claims of the patents-in-suit using the phrase "therapeutic metabolism" are invalid for indefiniteness.

53. A determination of claim indefiniteness is a legal conclusion that is drawn from the court's construction of the patent claims. *See Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). Every patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. Claims that are "not amenable to construction" or "insolubly ambiguous" are indefinite. *Datamize,* 417 F.3d at 1347. "[I]f reasonable efforts at claim construction prove futile," a claim term should be deemed indefinite. *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Claims are *required* to be "sufficiently precise" so that a potential competitor may "determine whether or not he is infringing ... ." *Morton Int'l v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993). Where a claim fails this test, it is invalid. *See id.*

C. **The patents-in-suit are unenforceable due to Wyeth's inequitable conduct during the prosecution of the relevant patent applications.**

54. The parties will litigate whether the patents-in-suit are unenforceable because of Wyeth's inequitable conduct during the prosecution of the patents-in-suit. Specifically, the parties will litigate whether Wyeth made material misrepresentations to or withheld information material to patentability from the PTO during the prosecution of the patents-in-suit, and, if so,

EXHIBIT B

IMPAX'S BRIEF STATEMENT OF WHAT IT INTENDS TO PROVE AT TRIAL

In addition to the facts not in dispute, Impax intends to submit proof, or make offers of proof,[1] at trial showing that:

1. Had this Court adopted Impax's proposed construction of the claim term "extended release formulation," Impax's proposed extended-release formulation of venlafaxine would not literally infringe the Wyeth patents-in-suit.

   a. Under Impax's proposed construction, the term "extended release formulation," as used in the patents-in-suit, means the specific combination of ingredients described repeatedly as "the invention" in the specification of the patents-in-suit: venlafaxine hydrochloride, microcrystalline cellulose ("MCC"), and, optionally, hydroxypropylmethylcellulose ("HPMC").

   b. Impax's proposed extended-release venlafaxine product does not include any MCC.

2. Had this Court adopted Impax's proposed construction of the claim term "extended release formulation," Impax's proposed extended-release formulation of venlafaxine would not infringe the Wyeth patents-in-suit under the doctrine of equivalents.

   a. Although Impax's extended-release venlafaxine product is bioequivalent to Wyeth's Effexor® XR product under FDA regulations, Impax's product is formulated differently from the Wyeth product, and contains different ingredients that perform different functions in different ways to achieve different results.

   b. Wyeth's Effexor® XR product is created through a process described in the specification of the patents-in-suit as "extrusion and spheronization." This process

[1] In light of the Court's recent claim-construction ruling, and in order to create a record in case of appeal, Impax also intends to make offers of proof regarding the evidence it would have presented regarding non-infringement and invalidity had the Court accepted Impax's proffered constructions of the disputed claim terms in the asserted claims of the patents-in-suit. In the interest of completeness, this list contains a description of Impax's offers of proof on such issues.

c. Further, because Dr. Sheskey's contribution of one of those three ingredients led to a breakthrough that permitted Wyeth to move forward with its work at a crucial stage, his contribution was significant.

d. Finally, by suggesting a specific ingredient that might succeed where other, similar ingredients had failed, he did more than explain a well-known concept or the current state of the art to Ms. Sherman.

10. Had this Court adopted Impax's proposed construction of the claim term "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma," and if the Court construes the preambles of the asserted claims as limiting claim scope, the asserted claims describing the "therapeutic metabolism" of venlafaxine would be invalid for indefiniteness. That claim term is not used by persons having skill in the art and has no meaning to such persons. Wyeth's pharmacokinetics expert conceded that he had never used the term in his career outside the context of this litigation.

11. Wyeth engaged in inequitable conduct in prosecuting the patents-in-suit, and accordingly that those patents should be unenforceable against Impax for the following three reasons:

a. The specification of the patents-in-suit makes the claim that, in two eight-week and one 12-week clinical studies, Wyeth's extended-release venlafaxine product showed a statistically significant improvement in incidence of nausea over conventional immediate-release venlafaxine. This was an unsolicited argument for patentability by Wyeth over the prior art describing the therapeutic benefits of immediate-release venlafaxine and methods of formulating extended-release pharmaceutical products. Impax intends to prove that this statement is false and was intended to mislead the PTO, for the following reasons:

- The two eight-week studies Wyeth cited did not even give patients immediate-release venlafaxine and thus could not have measured nausea associated with that drug against nausea associated with